



1651

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Khan et. al.

Serial No.: 10/029,206

Filed: December 21, 2001

For: OLIGOPEPTIDE TREATMENT OF ANTHRAX

Confirmation No.: 5353

Examiner: To be assigned

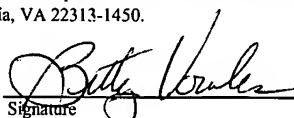
Group Art Unit: 1651

Attorney Docket No.: 2183-5222US

CERTIFICATE OF MAILING

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March 5, 2004
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Betty Vowles
Name (Type/Print)

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In compliance with the duty to disclose information material to patentability pursuant to 37 C.F.R. § 1.56, it is respectfully requested that this Information Disclosure Statement be entered and the documents listed on attached Form PTO-1449 or PTO/SB/08 be considered by the Examiner and made of record. Copies of the listed documents are enclosed pursuant to 37 C.F.R. § 1.98(a).

In accordance with 37 C.F.R. § 1.97(g) and (h), filing of this Information Disclosure Statement is not to be construed as a representation that a search has been made or an admission that the information cited herein is, or is considered to be, material to patentability as defined in 37 C.F.R. § 1.56(b). Further, no representation is made by Applicants herein that no other possible material information as defined in 37 C.F.R. § 1.56(b) exists.

U.S. Patent Documents

<u>U.S. Patent No.</u>	<u>Publication Date</u>	<u>Patentee</u>
#US- 4,977,244	12-11-1990	Muchmore et al.
#US- 5,677,275	10-14-1997	Lunardi-Iskandar et al.
#US- 5,877,148	03-02-1999	Lunardi-Iskandar et al.
#US- 5,958,413	09-28-1999	Anagnostopulos et al.
#US- 5,968,513	10-19-1999	Gallo et al.
#US- 5,997,871	12-07-1999	Gallo et al.
#US- 2003/0049273 A1	03-13-2003	Gallo et al.
#US- 6,583,109 B1	06-24-2003	Gallo et al.
#US- 6,596,688 B1	07-22-2003	Gallo et al.
#US- 6,620,416 B1	09-16-2003	Gallo et al.
#US- 2002/0064501	05-30-2002	Khan et al.
#US- 2002/0041871	04-11-2002	Brudnak
#US- 5,851,997	12-22-1998	Harris
#US- 6,489,296	12-03-2002	Grinnell et al.
US- 5,854,004	12-1998	Czemilofsky et al.
US- 6,361,992 B1	03-2002	Szkudlinski et al.

Foreign Patent Documents

<u>Document No.</u>	<u>Publication Date</u>	<u>Patentee</u>
#WO 01/10907 A2	02-15-2001	University of Maryland
#WO 01/11048 A2	02-15-2001	University of Maryland
#WO 01/72831	10-04-2001	Erasmus Universiteit
#2 706 772	12-30-1994	Vacsyn
#EP 1 138 692 A1	10/04/2001	Erasmus Universiteit Rotterdam
#EP 1 300 418	04-09-2003	Erasmus Universiteit

Serial No.: 10/029,206

		Rotterdam
#WO 98/35691	08-20-1998	Proscript, Inc.
#WO 02/085117	10-31-2002	Eisai Co., Ltd.
#DE 3715662	11-19-1987	The Wellcome Foundation Ltd.
#DE 19953339	05-17-2001	Goldham Pharma GmbH
#96/04008	02-15-1996	Government of the United States
#97/49373	12-31-1997	University of Maryland Biotechnology Institute
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#KANUNGO et al., Advanced Maturation of Heteropneustes Fossilis (Bloch) by Oral Administration of Human Chorionic Gonadotropin, J. Adv. Zool., 1999, pp. 1-5, Vol. 20.

#ROHRIG et al., Growth-stimulating Influence of Human Chorionic Gonadotropin (hCG) on Plasmodium falciparum in vitro, Zentralblatt Bakt, 1999, pp. 89-99, Vol. 289.

#TAK et al., NF-kappaB: a key role in inflammatory diseases, J Clin Invest., 2001, pp. 7-11, Vol. 107.

#TAN et al., The role of activation of nuclear factor-kappa B of rat brain in the pathogenesis of experimental allergic encephalomyelitis, *Acta Physiol Sinica*, 2003, pp. 58-64, Vol. 55.

#TOVEY et al., Mucosal Cytokine Therapy: Marked Antiviral and Antitumor Activity, *J. Interferon Cytokine Res.*, 1999, pp. 911-21, Vol. 19.

#ALBINI, A., et al., "Old drugs as novel angiogenesis inhibitors: Preclinical studies with NAC, hCG, EGCG and somatostatin," 17 *CLINICAL & EXPERIMENTAL METASTASIS* 739 (1999).

#BLACKWELL, Timothy S., et al., "The Role of Nuclear Factor-kB in Cytokine Gene Regulation," 17 *AM. J. RESPIR. CELL MOL. BIOL.* 3-9 (1997).

#KELLER, S., et al., "Human Chorionic Gonadotropin (hCG) Is a Potent Angiogenic Factor for Uterine Endothelial Cells *in Vitro*," 20(5-6) *PLACENTA*, page A37 (July 1999).

#KHAN, Nisar A., et al., "Inhibition of Diabetes in NOD Mice by Human Pregnancy Factor," 62(12) *HUMAN IMMUNOLOGY* 1315-1323 (December 2001).

#KHAN, Nisar A., et al., "Inhibition of Septic Shock in Mice by an Oligopeptide From the β -Chain of Human Chorionic Gonadotrophin Hormone," 63(1) *HUMAN IMMUNOLOGY* 1-7 (January 2002).

#MUCHMORE et al., Immunoregulatory Properties of Fractions from Human Pregnancy Urine: Evidence that Human Chorionic Gonadotropin is not Responsible, *The Journal of Immunology*, March 1997, pp. 881-86, Vol. 118, No. 3.

#MUCHMORE et al., Purification and Characterization of a Mannose-Containing Disaccharide Obtained from Human Pregnancy Urine, *Journal of Experimental Medicine*, December 1984, pp. 1672-85, Volume 160.

#PATIL, A., et al., "The Study of the Effect of Human Chorionic Gonadotrophic (HCG) Hormone on the Survival of Adrenal Medulla Transplant in Brain. Preliminary Study," 87 *ACTA NEUROCHIR (WIEN)* 76-78 (1987).

#SLATER, Lewis M., et al., "Decreased Mortality of Murine Graft-Versus-Host Disease by Human Chorionic gonadotropin," 23(1) *TRANSPLANTATION* 103-104 (January 1977).

Serial No.: 10/029,206

#WULCZYN, F. Gregory, et al., "The NF-kB/Rel and Ikb gene families: mediators of immune response and inflammation," 74(12) J. MOL. MED. 749-769 (1996).

#YAMAMOTO, Y., et al., "Role of the NF-kB Pathway in the Pathogenesis of Human Disease States," 1(3) CURRENT MOLECULAR MEDICINE 287-296 (July 2001).

Pursuant to 37 C.F.R. § 1.98(d), copies of the previously identified patents are not being provided since they were previously cited by or submitted to the Office in the following prior application:

Serial No.: 10/028,075

Filed: December 21, 2001

For: GENE REGULATOR, which application is being relied upon for an earlier filing date under 35 U.S.C. § 120.

In compliance with the duty to disclose information material to patentability pursuant to 37 C.F.R. § 1.56 & 1.175, Applicants offer hereby identifies the following listed copending applications naming the same inventor(s):

Attorney Docket No.: 3077-5951US
Serial No.: 10/409,027
Filing Date: 4/8/2003
Title: TREATMENT OF TRANSPLANT SURVIVAL

Attorney Docket No.: 3077-5952US
Serial No.: 10/409,032
Filing Date: 4/8/2003
Title: TREATMENT OF TRAUMA

Attorney Docket No.: 3077-5953US
Serial No.: 10/409,630
Filing Date: 4/8/2003
Title: TREATMENT OF MULTIPLE SCLEROSIS

Attorney Docket No.: 3077-5957US
Serial No.: 10/409,642
Filing Date: 4/8/2003
Title: TREATMENT OF ISCHEMIC EVENTS

Attorney Docket No.: 3077-5958US
Serial No.: 10/409,654
Filing Date: 4/8/2003
Title: TREATMENT OF NEUROLOGICAL DISORDERS

Serial No.: 10/029,206

Attorney Docket No.: 3077-5960US
Serial No.: 10/409,657
Filing Date: 4/8/2003
Title: STRATIFICATION

Attorney Docket No.: 3077-5956US
Serial No.: 10/409,659
Filing Date: 4/8/2003
Title: PEPTIDE COMPOSITIONS

Attorney Docket No.: 3077-5959US
Serial No.: 10/409,668
Filing Date: 4/8/2003
Title: ADMINISTRATION OF GENE-REGULATORY PEPTIDES

Attorney Docket No.: 3077-5955US
Serial No.: 10/409,671
Filing Date: 4/8/2003
Title: TREATMENT OF IATROGENIC DISEASE

Attorney Docket No.: 3077-5954US
Serial No.: 10/409,694
Filing Date: 4/8/2003
Title: TREATMENT OF BURNS

Attorney Docket No.: 3077-4618.1US
Serial No.: 10/678,995
Filing Date: 10/3/2003
Title: IMMUNOREGULATOR

Attorney Docket No.: 3077-6084US
Serial No.: 10/753,510
Filing Date: 1/7/2004
Title: IMMUNOREGULATORY COMPOSITIONS

Serial No.: 10/029,206

This Supplemental Information Disclosure Statement is believed to be filed before the mailing date of a first Office Action on the merits; therefore, no fee is due.

Respectfully submitted,



G. Scott Dorland, Ph.D.

Registration No. 51,622

Attorney for Applicant(s)

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Date: March 5, 2004

GSD/bv

Enclosures: Form PTO/SB/08

Document in ProLaw



PTO/SB/08A (10-01)

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 1 of 4

Complete if Known

Application Number	10/029,206
Filing Date	December 21, 2001
First Named Inventor	Khan et. al.
Group Art Unit	1651
Examiner Name	To be assigned
Attorney Docket Number	2183-5222US

U.S. PATENT DOCUMENTS

Examiner Initials *	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code ² (if known)			
		#US- 4,977,244	12-11-1990	Muchmore et al.	
		#US- 5,677,275	10-14-1997	Lunardi-Iskandar et al.	
		#US- 5,877,148	03-02-1999	Lunardi-Iskandar et al.	
		#US- 5,958,413	09-28-1999	Anagnostopoulos et al.	
		#US- 5,968,513	10-19-1999	Gallo et al.	
		#US- 5,997,871	12-07-1999	Gallo et al.	
		#US- 2003/0049273 A1	03-13-2003	Gallo et al.	
		#US- 6,583,109 B1	06-24-2003	Gallo et al.	
		#US- 6,596,688 B1	07-22-2003	Gallo et al.	
		#US- 6,620,416 B1	09-16-2003	Gallo et al.	
		#US- 2002/0064501	05-30-2002	Khan et al.	
		#US- 2002/0041871	04-11-2002	Brudnak	
		#US- 5,851,997	12-22-1998	Harris	
		#US- 6,489,296	12-03-2002	Grinnell et al.	
		US- 5,854,004	12-1998	Czernilofsky et al.	
		US- 6,361,992 B1	03-2002	Szkudlinski et al.	
		US-			

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ³ - Number ⁴ - Kind Code ⁵ (if known)				
		#WO 01/10907 A2	02-15-2001	University of Maryland		
		#WO 01/11048 A2	02-15-2001	University of Maryland		
		#WO 01/72831	10-04-2001	Erasmus Universiteit		
		#2 706 772	12-30-1994	Vacsyn		
		#EP 1 138 692 A1	10/04/2001	Erasmus Universiteit Rotterdam		

Examiner
SignatureDate
Considered

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¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

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		Application Number	10/029,206		
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Sheet	2	of	4	Attorney Docket Number	2183-5222US

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		#EP 1 300 418	04-09-2003	Erasmus Universiteit Rotterdam		
		#WO 98/35691	08-20-1998	Proscript, Inc.		
		#WO 02/085117	10-31-2002	Eisai Co., Ltd.		
		#DE 3715662	11-19-1987	The Wellcome Foundation Ltd.		
		#DE 19953339	05-17-2001	Goldham Pharma GmbH		
		#96/04008	02-15-1996	Government of the United States		
		#97/49373	12-31-1997	University of Maryland Biotechnology Institute		
		#97/49418	12-31-1997	University of Maryland Biotechnology Institute		
		#97/49432	12-31-1997	University of Maryland Biotechnology Institute		

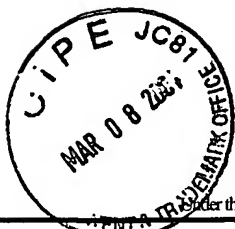
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¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

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**INFORMATION DISCLOSURE
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Sheet

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Group Art Unit	1651
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OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS

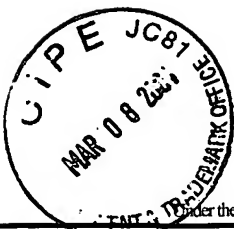
Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		#International Search Report, International Application No. PCT/NL02/00639, mailed August 4, 2003 (8 pages).	
		#CHRISTMAN et al., Nuclear factor kappaB: a pivotal role in the systemic inflammatory response syndrome and new target for therapy, Intens Care Med, 1998, pp. 1131-38, Vol. 24.	
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		#ROHRIG et al., Growth-stimulating Influence of Human Chorionic Gonadotropin (hCG) on Plasmodium falciparum in vitro, Zentralblatt Bakt, 1999, pp. 89-99, Vol. 289.	
		#TAK et al., NF-kappaB: a key role in inflammatory diseases, J Clin Invest., 2001, pp. 7-11, Vol. 107.	
		#TAN et al., The role of activation of nuclear factor-kappa B of rat brain in the pathogenesis of experimental allergic encephalomyelitis, Acta Physiol Sinica, 2003, pp. 58-64, Vol. 55.	
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Sheet

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OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		#ALBINI, A., et al., "Old drugs as novel angiogenesis inhibitors: Preclinical studies with NAC, hCG, EGCG and somatostatin," 17 CLINICAL & EXPERIMENTAL METASTASIS 739 (1999).	
		#BLACKWELL, Timothy S., et al., "The Role of Nuclear Factor-kB in Cytokine Gene Regulation," 17 AM. J. RESPIR. CELL MOL. BIOL. 3-9 (1997).	
		#KELLER, S., et al., "Human Chorionic Gonadotropin (hCG) Is a Potent Angiogenic Factor for Uterine Endothelial Cells <i>in Vitro</i> ," 20(5-6) PLACENTA, page A37 (July 1999).	
		#KHAN, Nisar A., et al., "Inhibition of Diabetes in NOD Mice by Human Pregnancy Factor," 62(12) HUMAN IMMUNOLOGY 1315-1323 (December 2001).	
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		#MUCHMORE et al., Immunoregulatory Properties of Fractions from Human Pregnancy Urine: Evidence that Human Chorionic Gonadotropin is not Responsible, The Journal of Immunology, March 1997, pp. 881-86, Vol. 118, No. 3.	
		#MUCHMORE et al., Purification and Characterization of a Mannose-Containing Disaccharide Obtained from Human Pregnancy Urine, Journal of Experimental Medicine, December 1984, pp. 1672-85, Volume 160.	
		#PATIL, A., et al., "The Study of the Effect of Human Chorionic Gonadotrophic (HCG) Hormone on the Survival of Adrenal Medulla Transplant in Brain. Preliminary Study," 87 ACTA NEUROCHIR (WIEN) 76-78 (1987).	
		#SLATER, Lewis M., et al., "Decreased Mortality of Murine Graft-Versus-Host Disease by Human Chorionic gonadotropin," 23(1) TRANSPLANTATION 103-104 (January 1977).	
		#WULCZYN, F. Gregory, et al., "The NF-kB/Rel and I κ B gene families: mediators of immune response and inflammation," 74(12) J. MOL. MED. 749-769 (1996).	
		#YAMAMOTO, Y., et al., "Role of the NF-kB Pathway in the Pathogenesis of Human Disease States," 1(3) CURRENT MOLECULAR MEDICINE 287-296 (July 2001).	

Examiner
SignatureDate
ConsideredPursuant to 37 C.F.R. § 1.98(d), copies of the previously identified patents are not being provided since they were previously cited by or submitted to the Office in the following prior application:

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